

PCT COOPERATION TREATY

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From the INTERNATIONAL BUREAU

NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

F. B. RICE & CO.
605 Darling Street
Balmain, NSW 2041
AUSTRALIE

RECEIVED

22 AUG 2000

F. B. RICE & CO.

Date of mailing (day/month/year) 04 August 2000 (04.08.00)	
Applicant's or agent's file reference 100512	IMPORTANT NOTIFICATION
International application No. PCT/AU00/00689	International filing date (day/month/year) 19 June 2000 (19.06.00)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 18 June 1999 (18.06.99)
Applicant MACQUARIE RESEARCH LTD et al	

- The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
- An asterisk(*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
18 June 1999 (18.06.99)	PQ 1056	AU	11 July 2000 (11.07.00)

ENTERED IN DATA BASE

23/8/00

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

G. Bähr

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:

F B RICE & CO
605 Darling Street
Balmain, NSW 2041
AUSTRALIE

RECEIVED

11 JAN 2001

F. B. RICE & CO.

Date of mailing (day/month/year)
28 December 2000 (28.12.00)

Applicant's or agent's file reference
100512

IMPORTANT NOTICE

International application No.
PCT/AU00/00689

International filing date (day/month/year)
19 June 2000 (19.06.00)

Priority date (day/month/year)
18 June 1999 (18.06.99)

Applicant
MACQUARIE RESEARCH LTD et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
AG,AU,BZ,DZ,KP,KR,MZ,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CR,CU,CZ,DE,DK,DM,EA,EE,EP,ES,FI,GB,GD,
GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,
NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
28 December 2000 (28.12.00) under No. WO 00/78781

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

J. Zahra

Facsimile No. (41-22) 740.14.35

Telephone No. (41-22) 338.83.38

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00689

A. CLASSIFICATION OF SUBJECT MATTERInt. Cl. ⁷: C07H 21/02, 21/04; C12N 15/11, C12Q 1/68

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Medline, USPTO Full File: keyword search (Giardia, lamblia, 18s rRNA, nucleic acid, oligonucleotide)**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5558989 (AMOCO CORPORATION) 24 September 1996 See whole document.	1-18
X	Molecular and Biochemical Parasitology, 1992, vol 54, no 1 pages 73-86 Weiss JB, van Keulen H, Nash TE, "Classification of subgroups of Giardia lamblia based upon ribosomal RNA gene sequence using polymerase chain reaction". See whole document.	1-18

☒ Further documents are listed in the continuation of Box C
 ☒ See patent family annex

* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
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Date of the actual completion of the international search
22 August 2000Date of mailing of the international search report
29 AUG 2000Name and mailing address of the ISA/AU
AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaustalia.gov.au
Facsimile No. (02) 6285 3929

Authorized officer

O.L. CHAI
Telephone No. (02) 6283 2482

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00689

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Applied and Environmental Microbiology, vol 63 no 1, 1997, pages 106-114 Rochelle PA et al, "Comparison of primers and optimization of PCR conditions for detection of <i>Cryptosporidium parvum</i> and <i>Giardia lamblia</i> in water" See whole document.	1-18

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU00/00689

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
US	5558989	AT	144557	AU	74295/91	CA	2040583
		CA	2040802	DE	69122800	EP	453290
		JP	5068594	JP	3048665		
END OF ANNEX							

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing (day/month/year)

07 February 2001 (07.02.01)

International application No.

PCT/AU00/00689

Applicant's or agent's file reference

100512

International filing date (day/month/year)

19 June 2000 (19.06.00)

Priority date (day/month/year)

18 June 1999 (18.06.99)

Applicant

DORSCH, Matthias, Rudolf et al

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

11 January 2001 (11.01.01)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

R. E. Stoffel

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 100512	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU00/00689	International Filing Date (<i>day/month/year</i>) 19 June 2000	Priority Date (<i>day/month/year</i>) 18 June 1999
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ C12N 15/11; C12Q1/68; C07H 21/02, 21/04		
Applicant MACQUARIE RESEARCH LTD et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- | | | |
|------|-------------------------------------|---|
| I | <input checked="" type="checkbox"/> | Basis of the report |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input checked="" type="checkbox"/> | Certain observations on the international application |

Date of submission of the demand 11 January 2001	Date of completion of the report 5 July 2001
Name and mailing address of the IPEA AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer K. LEVER Telephone No. (02) 6283 2254

I. Basis of the report

1. With regard to the elements of the international application:*
- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed, #
 pages , as amended (together with any statement) under Article 19,
 pages , filed with the demand, --
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of
2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished
4. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. *Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 3-9, 11-18	YES
	Claims 1, 2, 10	NO
Inventive step (IS)	Claims 3-9, 11-18	YES
	Claims 1, 2, 10	NO
Industrial applicability (IA)	Claims 1-18	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

Novelty and inventive step

The following documents were cited in the international search report:

- D1 US 5558989
 D2 Molecular and Biochemical Parasitology 1992, vol 54, pages 73-86
 D3 Applied and Environmental Microbiology 1997, vol 63, pages 106-114

The invention is directed to the detection of *Giardia lamblia* using nucleic acid probes. Claims 3-9 and 11-18 are directed to probes with specific nucleotide sequences. These claims meet the criteria for novelty and inventive step under PCT articles 33(2) and (3) because none of the citations disclose or render obvious the claimed subject matter.

Claims 1, 2 and 10 lack novelty in light of D1. The citation discloses a method of selectively detecting *Giardia lamblia* using nucleic acid probes which hybridize to the 18S ribosomal RNA or DNA (column 1 lines 53-60, Figure 1, column 2, lines 26-37, column 3 line 46 to column 4 line 4, Example 1, Table 1).

Claims 1, 2 and 10 lack novelty in light of D2. The citation uses nucleotide sequences based upon the 18S ribosomal RNA gene in hybridization reactions (abstract, page 74 - *PCR amplification*, Table 1, Figure 5).

Claims 1, 2 and 10 lack novelty in light of D3. The citation discloses hybridization with oligonucleotide probes specific for *Giardia lamblia* based upon the 18S rRNA gene (abstract, page 106 column 2, page 108 column 2, Table 3, page 110 column 2 - *specificity and sensitivity*).

Industrial applicability

Claims 1-18 meet the criteria set out in PCT Article 33(4) for industrial applicability.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claims 1, 2 and 10 are not fully supported by the description. The specification only discloses certain oligonucleotide probes which can hybridise to unique 18S rRNA/rDNA sequence of *Giardia lamblia*. The claims in their present form include all oligonucleotide molecules which hybridises selectively to the 18S rRNA/rDNA sequence.

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REC'D 20 JUL 2001

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 100512	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU00/00689	International Filing Date (<i>day/month/year</i>) 19 June 2000	Priority Date (<i>day/month/year</i>) 18 June 1999
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ C12N 15/11; C12Q1/68; C07H 21/02, 21/04		
Applicant MACQUARIE RESEARCH LTD et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of 4 sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of sheet(s).
3.	This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application

Date of submission of the demand 11 January 2001	Date of completion of the report 5 July 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer K. LEVER Telephone No. (02) 6283 2254

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU00/00689

I. Basis of the report

1. With regard to the **elements** of the international application:*
- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
 pages , as amended (together with any statement) under Article 19,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of
2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
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- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
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- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.
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** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU00/00689

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 3-9, 11-18	YES
	Claims 1, 2, 10	NO
Inventive step (IS)	Claims 3-9, 11-18	YES
	Claims 1, 2, 10	NO
Industrial applicability (IA)	Claims 1-18	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

Novelty and inventive step

The following documents were cited in the international search report:

- D1 US 5558989
D2 Molecular and Biochemical Parasitology 1992, vol 54, pages 73-86
D3 Applied and Environmental Microbiology 1997, vol 63, pages 106-114

The invention is directed to the detection of *Giardia lamblia* using nucleic acid probes. Claims 3-9 and 11-18 are directed to probes with specific nucleotide sequences. These claims meet the criteria for novelty and inventive step under PCT articles 33(2) and (3) because none of the citations disclose or render obvious the claimed subject matter.

Claims 1, 2 and 10 lack novelty in light of D1. The citation discloses a method of selectively detecting *Giardia lamblia* using nucleic acid probes which hybridize to the 18S ribosomal RNA or DNA (column 1 lines 53-60, Figure 1, column 2, lines 26-37, column 3 line 46 to column 4 line 4, Example 1, Table 1).

Claims 1, 2 and 10 lack novelty in light of D2. The citation uses nucleotide sequences based upon the 18S ribosomal RNA gene in hybridization reactions (abstract, page 74 - *PCR amplification*, Table 1, Figure 5).

Claims 1, 2 and 10 lack novelty in light of D3. The citation discloses hybridization with oligonucleotide probes specific for *Giardia lamblia* based upon the 18S rRNA gene (abstract, page 106 column 2, page 108 column 2, Table 3, page 110 column 2 - *specificity and sensitivity*).

Industrial applicability

Claims 1-18 meet the criteria set out in PCT Article 33(4) for industrial applicability.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claims 1, 2 and 10 are not fully supported by the description. The specification only discloses certain oligonucleotide probes which can hybridise to unique 18S rRNA/rDNA sequence of *Giardia lamblia*. The claims in their present form include all oligonucleotide molecules which hybridises selectively to the 18S rRNA/rDNA sequence.